

APPENDIX F

SUMMARY OF EXTERNAL TECHNICAL PEER REVIEW

In January 1993, responding to recommendations in the report *Safeguarding the Future: Credible Science, Credible Decisions*, Administrator William Reilly issued an Agency-wide policy for peer review. Administrator Carol Browner confirmed and reissued the policy on June 7, 1994. As a result, USEPA established a Standard Operating Procedure (SOP) for the organization and conduct of peer reviews. This peer review procedure is contained in the *Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents*, Office of Prevention, Pesticides and Toxic Substances, U.S. Environmental Protection Agency, October 1, 1996 - September 30, 1997.

The objective of the peer review is to uncover any technical problems or unresolved issues for use in revising a preliminary work product so that the final work product will reflect sound technical information and analyses. Peer review is also considered a process for enhancing a scientific or technical work product. A peer review is an objective, critical review of an Agency scientific and technical work product by an independent peer reviewer or reviewers. An independent peer reviewer is an expert who was not associated with the generation of the specific work product either directly, by substantial contribution to its development, or indirectly, by consultation during the development of the specific product. The Agency chose 'a balanced *ad hoc* panel of independent experts from outside the Agency' as the mechanism for obtaining a peer review panel. The objective of a 'well balanced panel of independent peer reviewers' is to assure an objective, fair, and responsible evaluation of the work product.

Over the past six years, the EPA Design for the Environment Garment and Textile Care Program (GTCP) has collaborated with a group of key stakeholders, including representatives of industry, research, environmental, labor and public interest groups. At EPA's request, these stakeholders nominated technical peer reviewers that had expertise in one or more areas: Technology and Economics; Exposure Assessment; Hazard Assessment; and Risk Assessment. Thirty-nine reviewers were selected from the list and the official peer review period began on June 24, 1997 with a conference call with stakeholders. All of the stakeholders' first and/or second and/or third choice nominees in each area of expertise were chosen for the review. The reviewers were given four weeks to complete their review and return comments. Thirty-six reviewers provided comments on the draft CTSA. In the course of the review, four reviewers withdrew from the panel. Reasons for withdrawal from the peer review process included lack of available time for a thorough review, or lack of specialized expertise necessary to adequately review the material presented in the CTSA document.

This report presents the general approach and considerations taken into account for conducting the peer review of the *Cleaner Technologies Substitutes Assessment for Professional Fabricare Processes*. The objective of the peer review was to uncover any technical problems or unresolved issues so that the final will reflect sound technical information and analyses. The peer review was also used to enhance the scientific and technical content of the CTSA. According to the *Standard Operating Procedures for Peer Review of Major Scientific and Technical Documents*, the Cleaner Technologies Substitutes Assessment was considered to be a major scientific and technical work product, and as such required an independent peer review. A multi-disciplinary group of experts corresponding to the disciplines that contribute to complex Agency decisions was necessary for a full and complete peer review. This Appendix describes the procedures used for obtaining the expert review of the CTSA.

During the development of the CTSA, EPA's Design for the Environment Garment and Textile Care Program collaborated with a group of stakeholders, including manufacturers of chemicals used in the dry cleaning process, formulators, dry cleaners, and others to assist EPA in characterizing the hazards, uses, exposures, and risks of substances used in the dry cleaning industry, as well as economic considerations and the identification of pollution prevention opportunities. The group of stakeholders which contributed to the development of the CTSA document were contacted in late May and early June of 1997. Stakeholders were asked to submit a list of peer review panelists in order of preference for each of the major technical areas of the CTSA: Technology and Economics; Exposure Assessment; Hazard Assessment; and Risk Assessment. Each proposed candidate peer reviewer was required to have training and/or experience in one or more of the following areas: 1) occupational and general exposure assessment; 2) exposure modeling techniques; 3) chemical monitoring; 4) occupational health; 5) industrial hygiene; 6) toxicology, including environmental (aquatic); 7) environmental epidemiology; 8) risk assessment; 9) economics, finance, accounting; 10) marketing; 11) comparative cleaning technologies (e.g., wet methods); 12) the dry cleaning industry, including equipment and processes used, practices employed, etc.; and 13) chemistry (product, engineering, environmental fate).

At a minimum, candidate peer reviewers were required to be free of conflict of interest, be considered experts within their respective fields of study, have specific knowledge of the methodologies employed in the development of risk assessments (e.g., modeling techniques), have specific knowledge of the chemicals of concern (e.g., PCE), and, where appropriate, have some knowledge of the dry cleaning industry. EPA attempted to contact candidate peer reviewers to confirm their interest in reviewing the document and their availability throughout the months of July and August. For each stakeholder group that nominated candidate peer reviewers and ranked their nominees, at least their first, second, and third ranked nominees in each area of expertise were called. Candidate reviewers were contacted to determine their availability and willingness to take part in the peer review process. The CTSA peer review panel consisting of 40 peer reviewers was finalized by EPA on July 21, 1997. A list of the individuals on the peer review panel is contained in Exhibit F-1. This final peer review panel incorporated a large and well balanced independent panel of experts from the dry cleaning industry and the environmental and scientific communities.

EPA prepared a separate packet of documentation for the peer reviewers, including a confirmation letter and non-disclosure agreement. Packets were sent out to all 40 peer reviewers by Federal Express on July 21, 1997. All reviewers were requested to fax their signed non-disclosure agreements to USEPA by July 24, 1997.

A conference call took place on July 24, 1997. Participants included EPA and key stakeholders listed in Exhibit F-2. During the call, EPA announced the release of the CTSA document for peer review. In the call, EPA stated that a well-balanced panel was chosen since all of the stakeholders' first and/or second and/or third choice nominees in each area of expertise were chosen for the review.

Exhibit F-1. Final CTSA Peer Review Panel

Mr. Ken C. Adamson, General Manager
Langley Parisian

Frank Arnold, Ph.D.

Charlene Bayer, Ph.D.
Georgia Tech Research Institute

Arnold Brown, M.D.

Pamela Christenson
Wisconsin Dept of Dev

Dick Clapp, Sc.D., M.P.H.
Boston University School of Public Health
Dept of Environmental Health

James Cone, M.D., M.P.H.

Elden Dickinson
Michigan Department of Environmental Quality

Paul Dugard, Ph.D.[‡]
ICI Americas, Inc.

Diane Echeverria
Battelle Seattle Operations

Adam Finkel, Ph.D.
Director, OSHA Health Standards Directorate
US Department of Labor

George Gray, Ph.D.
Harvard Center for Risk Analysis
Harvard School of Public Health

Dale Hattis, Ph.D.
Center for Technology, Environment, & Development
(CENTED)
Clark University

Ms. Chris Hayes
Greater Chicago P2 Program, MWRD

Denny Hjeresen, Ph.D.
Los Alamos National Labs

Rudolf Jaeger, Ph.D.
Environmental Medicine, Incorporated

Ellen Kirrane
Hunter College Center for Occup & Envir Health

Dr. Josef Kurz [‡]
Schloss Hohenstein

Jack Lauber, P.E.-D.A.A.E.E.
Consulting Engineer

James Melius, M.D., Ph.D.
Director
NY State Laborer's Health & Safety Trust Fund

Frank Mirer, Ph.D.
Director, Health & Safety Dept., UAW

Kenneth Mundt, Ph.D.
Umass, Dept. Of Biostatistics & Epidemiology
School of Public Health & Health Sciences

D. Warner North, Ph.D.
Decision Focus Inc.

Peter Orris, M.D.
Div. Of Occup. Med/Cook County Hospital

David Ozonoff, M.D., M.P.H.
Boston University School of Public Health
Dept of Environmental Health

Andrew Persily, Ph.D.[‡]
NIST

Routt Reigart, M.D.[‡]
Medical University of South Carolina

Charles Riggs, Ph.D.
Texas Women's University, Department of Fashion &
Textiles

Judy Schreiber, Ph.D.
NY Dept of Health

Tom Starr, Ph. D.
Environ Corp.

Exhibit F-1. Final CTSA Peer Review Panel (Continued)

Mike Tatch
Tatch Technical Services

Kimberly Thompson, Sc.D.
Consultant
Harvard Center for Risk Analysis

Joel Tickner
MSC/U Massachusetts Lowell

Greg Traynor
T. Marshall Associates

Arthur Upton, M.D.
Environmental & Occupational Health Sciences Inst.

David Votaw
Education and Information Division (C15)
National Institute for Occupational Safety and Health

Clifford Weisel, Ph.D.
Associate Professor
Deputy Director
Exposure Measurement and Assessment Division
Environmental and Occupational Health Sciences
Institute

Noel Weiss, M.D., Dr. P.H.
University of Washington
School of Health & Comm. Med.
Department Of Epidemiology

Manfred Wentz, Ph.D.
Chairperson, AATCC Research Committee
RA43: Dry Cleaning

Kathleen Wolf, Ph.D.
Institute for Research and Technical Assistance

‡ Reviewer did not submit peer review comments to EPA.

Note: No conflicts existed with any peer reviewers.

Exhibit F-2. Teleconference Attendees for CTSA Announcement - Held July 24, 1997

Name	Affiliation/Address
Mary Scalco, Bill Fisher	International Fabricare Institute
Bill Seitz	Neighborhood Cleaners Assoc., Intl.
Ross Beard	Fabricare Legislative & Regulatory
Steve Risotto	Centers for Emission Control
Gary Baise	Baise & Miller
Eric Frumin	Union of Needletrades, Industrial and Textile Employees
David DeRosa, Jack Weinberg	Greenpeace
Moon Jong Chun	Federation of Korean Drycleaning Association
Cindy Stroup, Lynne Blake-Hedges, Mary Ellen Weber	U.S. Environmental Protection Agency
Melinda Armbruster, Brandon Wood	Battelle Memorial Institute

Copies of the peer review CTSA document were sent to peer reviewers by Federal Express on July 24, 1997. Enclosed in each package sent to the peer reviewer was a letter of transmittal, a reminder to return their signed non-disclosure agreement, a peer review guidance document, and an alphabetized list of CTSA references. The peer review guidance document was a statement of work seeking informed comment on identified issues to properly focus the efforts of the peer reviewers and to assist them in their review.

Peer reviewers were asked to return their comments by August 25, 1997. Verbatim comments from peer reviewers were compiled and sorted by reviewer and by CTSA chapter to which they referred. Attribution of each reviewer's comments was kept anonymous. In a few cases, text was omitted from the original comment in order to facilitate reviewer anonymity. Where a comment cited a reference that was not complete, the reference was listed in square brackets following the comment.

In order to ensure correct transcription of all comments, all comments were checked against the original reviewer's submission to ensure that the text remained unchanged.

During the course of the review, four reviewers withdrew from the panel. Dr. Roult Reigart withdrew from the peer review process on August 1, 1997, Dr. Andrew Persily withdrew on August 22, 1997, Dr. Josef Kurz withdrew on August 28, 1997, and Dr. Paul Dugard did not respond. It was not possible to replace these four reviews since there was not adequate time remaining in the review cycle for replacements to complete a substantive review. Because the peer review panel was so large, the attrition of the four reviewers during the review process did not affect the balance of the panel nor the integrity of the review.

Exhibit F-3 presents summary statistics on the number of comments and number of pages of comments received. These statistics are separated into the following categories: general comments on CTSA document, comments on the executive summary, Chapters 1-8, and Appendixes A-D. There was a total of 1,855 comments comprising 340 pages. Of these 1,855 comments, there was a total of 208 editorial comments. The editorial comments included spelling changes and other minor structural modifications to the document.

The reviewers were given 4 weeks to complete their review and return comments to USEPA. Peer reviewer comments were compiled and sent to the USEPA CTSA Workgroup for disposition. The USEPA CTSA Workgroup reviewed all comments to determine the necessary changes to the CTSA as a result of the comments. The workgroup drafted responses to every peer review comment. The peer review comments and responses are included in the USEPA document, *Response to Technical Peer Review Comments*, EPA 744-P-98-001, June 1998.

USEPA feels that this extensive and rigorous technical review by a stellar panel of stakeholder-nominated reviewers has improved the quality of the CTSA and ensured that its conclusions are valid and based on sound science.

Exhibit F-3. Summary Statistics on CTSA Comments from CTSA Peer Review Panel

Section	Complete Set of Comments	
	# of Pages	# of Comments
General	49	181
Executive Summary	12	67
Chapter 1	56	328
Chapter 2	32	194
Chapter 3	60	357
Chapter 4	61	375
Chapter 5	12	61
Chapter 6	17	82
Chapter 7	10	50
Chapter 8	12	71
Appendix A	13	62
Appendix B	1	6
Appendix C	4	20
Appendix D	1	1
Total	340	1855